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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,219	07/26/2000	Jeffrey Browning	A046 US	7978

7590

08/16/2002

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,219

Applicant(s)

BROWNING ET AL.

Examiner

Misook Yu

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above claim(s) 28-30, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-27 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 9
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Newly submitted claims 30, 34 and 35 are directed to group II and III in Restriction/Elections (Paper No. 4) mailed on 01/04/2002 respectively and claims 27 and 28 are drawn to non-elected species. See page 2 lines 1-5 of the Office Action mailed on 02/22/2002 (Paper NO. 8). Also note page 1 line 2 of Response to Restriction Requirement filed on 10-31-2001 (Paper NO. 5) Restriction/Elections (Paper No. 4) mailed on 01/04/2002. Accordingly, claims 30, 34 and 35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 28 and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 20-35 are pending and claims 20-27 and 31-33 are examined on merits as they are drawn to the elected species of soluble LT beta receptor.

Claim Rejections - 35 USC § 112

Claims 20-27, and 31-33 remain rejected, for the reasons set forth at page 4 line 2 to page 5 line 9 in the Office Action mailed on 02/22/2002 (Paper NO. 8), under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The new claims are now drawn to method for tumor treatment (follicular lymphoma, specified in claim 21) comprising the administration to a subject (mammal of claim 24 or human of claim 25) of an effective amount of a composition comprising a soluble lymphotoxin (LT)-beta receptor as an elected species (claims 22 and 23) with various structural characteristic as specified in claims 26 and 27, which inhibits the interaction between LT-beta and its receptor and claims 31-33 further specify additional known cancer treatment (chemotherapy in claim 31, radiation treatment in claims 32 and 33, bone marrow transplantation in claim 33).

Applicant argues that the rejection should be withdrawn because: 1) the claims no longer recite the term "therapeutically"; 2) applicant elected a species, a soluble LT beta receptor. As for 1) argument above, the claims are still drawn to method to treat a tumor using an effective amount of composition and the specification does not teach what is an effective amount of a soluble LT beta receptor or a composition for the purpose stated in preamble of the claims. See page 4 lines 2-7 of the Office Action mailed on 02/22/2002 (Paper NO. 8) and applicant did not overcome this rejection in the amendment filed on 05/28/2002. The following is reiteration of the prior Office Action on merits: Applicant already stated that it takes undue experimentation ("extensive experiments" involving "pre-clinical and clinical trial") to determine the effective ("beneficial") dosage. As for the 2) argument above the newly submitted claims are now drawn to cancer treatment using a composition that inhibits the interaction between LT-beta and its receptor and applicant elected a soluble lymphotoxin beta receptor as a species used in the methods of currently examined claims. The specification does not teach any composition for accomplishing the purpose stated in the preamble of the claims. Note the paragraph bridging pages 4 and 5 of the Office Action mailed on 02/22/2002 (Paper NO. 8), and Table 1 and Example 1 of the specification at page 11. The chimeric soluble receptor used for the Experiment 1 and Table 1 at page 11 of the specification reduces lymph node weight. The following points are reiteration of the first Office Action on merits. "Demonstration the smaller LN weight cannot alone support the predictability of the method" for cancer treatment (Office Action mailed on 02/22/2002 at page 4 lines 18-20) either using the chimeric soluble receptor in Table 1 or any other composition in the specification. Neither the specification nor any prior art teaches that reduced lymph node weight in the model mice used is indicative of tumor reduction. The applicant did not argue this more important point in the amendment filed May 28, 2002. It is recognized in the art that cancer treatment is not trivial matter as reasons set forth in the paragraph bridging page 4 and 5 of the first Office Action on merits. The specification does not teach: (1) if the mice that received control developed tumor in the lymph node samples; (2) whether the reduced lymph node weight of the mice received the chimeric protein is a result of shrinkage of lymph nodes due to absence of LT-beta-

R signaling which is important for maintaining normal lymph node function and size (see page 2 line 9 of the specification); (3) any evidence the reduced lymph node weight is indication of reduction of tumor. Further, Office Action mailed on 02/22/2002 at page 5 line 5 stated that the specification does not teach method using broadly defined "blocking agent" but the specification discloses "**only a**" soluble LT receptor, which was used in only experiment in the specification the Experiment 1 (Table 1) of the specification.

Applicant did not overcome the examiner's main point of rejection, which is the specification is not enabled for cancer treatment using the elected species or any other composition that inhibits the interaction between the receptor and the ligand, and cancer treatment is unpredictable and difficult. Applicant did not argue about the examiner's point that the specification at Table 1 does not disclose any data that enables any cancer treatment method. See lines 8 and 9 of the Office Action. The specification failed to teach any method of cancer treatment using either a soluble LT beta receptor or the chimeric receptor used in Table 1 and the Amendment filed on May 28, 2002 did not overcome this rejection.

New Grounds of and Objection and Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-27 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 recites "an effective amount" in line 2 but it is not clear what the metes and bounds are for an effective amount. The specification does not define what the

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metes and bounds of a composition which inhibits the interaction between LT-beta and its receptor for the purpose stated in preamble.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Misook Yu
August 14, 2002

Mary E. Mosher
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